EXHIBIT 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 31, 2016

ROCHE DIABETES CARE, INC.
KHONE SAYSANA
REGULATORY AFFAIRS PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS IN 46250-0457

Re: K160944
Trade/Device Name: ACCU-CHEK Guide Blood Glucose Monitoring System, ACCU-CHEK Guide Control Solutions
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: July 15, 2016
Received: July 18, 2016

Dear Mr. Saysana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160944

Device Name
Accu-Chek Guide Blood Glucose Monitoring System
Accu-Chek Guide Control Solutions

Indications for Use *(Describe)*
The Accu-Chek Guide Blood Glucose Monitoring System is comprised of the Accu-Chek Guide meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.
The Accu-Chek Guide Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.
The Accu-Chek Guide Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.
This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.
Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide Control Solutions are for use with the Accu-Chek Guide Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

k160944

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter Name, Address, Contact

Roche Diabetes Care, Inc.
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7593
Contact Person: Khone Saysana
Date Prepared: August 30, 2016

2. Device Name

Proprietary names: Accu-Chek Guide Blood Glucose Monitoring System
Accu-Chek Guide control solutions

Classification name:
Glucose dehydrogenase, glucose test system (21 C.F.R. § 62.1345); Class II
Single (Specified) Analyte Controls (Assayed and Unassayed) (21 CFR § 862.1660); Class I

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase
JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

3. Predicate Device

Accu-Chek Aviva Connect Blood Glucose Monitoring System (k141867), concurrence received on March 3, 2015.
The Accu-Chek Aviva Controls (k043474), concurrence received on April 27, 2005.

The Accu-Chek Aviva Connect Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Accu-Chek Aviva Connect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

4. Device Description

The Accu-Chek Guide System consists of the following:

- Accu-Chek Guide meter
- Accu-Chek Guide test strips
- Accu-Chek Guide control solutions (previously cleared in k043474)

The Accu-Chek Guide Blood Glucose Monitoring System makes use of the Accu-Chek Guide test strips, the Accu-Chek Guide meter, and the Accu-Chek Guide control solutions. This system is a single-patient use blood glucose monitoring system intended to be used to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. It should be noted that the Accu-Chek Guide control solutions are identical to the Accu-Chek Aviva control solutions that were cleared previously in k043474. The name has simply been updated to reflect their use with the Accu-Chek Guide system.

The components of the Accu-Chek Guide Blood Glucose Monitoring System are shown below:

The ACCU-CHEK Guide Meter

Front View | Back View | Side View

1. **Display**
   Shows results, messages, and test results stored in memory.
2. **Back Button**
   Returns to a previous display or field.
3. **Up Arrow and Down Arrow Buttons**
   Press to move between menu options or to increase or decrease numbers.
4. **Power/Set/OK Button**
   Turns meter on or off and sets options.
5. **Test Strip Slot with Light**
   Insert test strip here.
6. **Battery Door**
   Flip open to replace batteries.
7. **Micro USB Port**
   Transfers data from the meter to a computer (PC).
8. **Test Strip Ejector**
   Press to remove test strip.

9. Test Strip Container*

10. Metallic End
Insert this end into meter.

11. Yellow Edge
Touch blood drop or control solution here.

12. Control Solution Bottle*

13. Batteries

14. USB Cable*
Connects the meter to a PC.

*Some items may not be included in the kit. They are a separate purchase.

bG Measurement Technology Description

The enzyme on the test strip, an FAD-dependent glucose dehydrogenase (GDH) expressed in A. Oryzae, converts the glucose in the blood to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and the environmental conditions are evaluated using AC and DC signals.

5. Intended Use

The Accu-Chek Guide Blood Glucose Monitoring System is comprised of the Accu-Chek Guide meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.
The Accu-Chek Guide Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.
The Accu-Chek Guide Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.
Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide Control Solutions are for use with the Accu-Chek Guide Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

6. Substantial Equivalence

The Accu-Chek Guide system substantially equivalent to the Accu-Chek Aviva Connect system. Below is a table that provides a comparison between the Accu-Chek Guide system and its predicate device.

Similarities and Differences Table

	Accu-Chek Guide (k160944)	**Accu-Chek Aviva Connect (k141867)**
Indications for Use	Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.	Quantitative measurement of glucose (sugar) in fresh capillary whole blood samples.
Alternate Site Testing	Palm and Upper arm	None
Enzyme	FAD-GDH	Mut. Q-GDH
Test Principle	Amperometric Detection	Amperometric Detection
Primary Container (Vial)	Black, flip top oval vial, holds up to 50 strips Closed vial height: 51 mm Width at widest point: 18.3 mm Width at narrowest point: 15.3 mm	White, flip top vial, holds up to 50 strips Closed vial height: 52.8 mm Outer diameter: 30.15 mm Inner diameter: 28.15 mm
Sample Volume	600 nanoliters	600 nanoliters
Measurement Range	20 – 600 mg/dL	20 – 600 mg/dL

	Accu-Chek Guide (k160944)	**Accu-Chek Aviva Connect (k141867)**
Hematocrit Range	10 – 65%	10 – 65%
Operating Temperature Range	6 – 45 °C	14 – 38 °C
Operating Relative Humidity Range	10 – 90%	10 – 80%
Maximum Altitude	10,150 feet	10,000 feet
Underdose Detection	Yes	Yes
Auto Control Solution Identification	Yes	Yes
Control Solutions	Aqueous, 2 Levels, cleared in k043474	Aqueous, 2 Levels, cleared in k043474
Strip Light	Yes	No
Strip Ejector	Yes	No
Connectivity	USB for PC connectivity and BLE (Bluetooth Low Energy) for wireless connectivity	USB for PC connectivity and BLE (Bluetooth Low Energy) for wireless connectivity
Coding	No	No

ACCU-CHEK Guide Controls Comparison

	Accu-Chek Guide Controls (k160944)	**Accu-Chek Aviva Controls (k043474)**
Intended Use	For use with the Accu-Chek Guide Monitoring System	For use with the Accu-Chek Aviva Plus Monitoring System
Control Type	Aqueous	Aqueous
Ingredients/Compostion	Control solutions are identical	
Control Level 1 Target	45 mg/dL	45 mg/dL
Control Level 2 Target	297 mg/dL	307 mg/dL
Unopened Shelf-life storage	24 months	24 months

7. Data demonstrating substantial equivalence

Performance testing on the Accu-Chek Guide system demonstrated that the device meets the performance requirements for its intended use. The data demonstrate that the system is substantially equivalent to the predicate device.

Below is the user performance data for the system:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
8/12 (66.7%)	12/12 (100%)	12/12 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20 %
63/108 (58.3%)	103/108 (95.4%)	107/108 (99.1%)	108/108 (100%)

Below is the user performance Palm AST data for the system:

Results for glucose concentrations less than 75 mg/dL

Alternate Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
Palm	8/9 (88.9%)	9/9 (100%)	9/9 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL

Alternate Site	Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20 %
Palm	175/363 (48.2%)	308/363 (84.8%)	356/363 (98.1%)	362/363 (99.7%)

Below is the user performance Upper Arm AST data for the system:

Results for glucose concentrations less than 75 mg/dL

Alternate Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
Upper Arm	7/10 (70%)	10/10 (100%)	10/10 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL

Alternate Site	Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20 %
Upper Arm	156/355 (43.9%)	281/355 (79.2%)	337/355 (94.9%)	351/355 (98.9%)

Below is the repeatability (within lot) precision for the system:

Blood	**1**	**2**	**3**	**4**	**5**
N	300	300	300	300	300
Mean [mg/dL]	40.5	81.7	132.1	206.7	330.2
SD [mg/dL]	1.4	2.0	2.8	5.4	8.6
CV [%]	3.5	2.4	2.1	2.6	2.6

Below is the reproducibility (intermediate or day-to-day) precision for the system:

Control solutions	**Low**	**Mid**	**High**
N	300	300	300
Mean [mg/dL]	44.9	116.6	297.4
SD [mg/dL]	1.4	2.8	6.8
CV [%]	3.1	2.4	2.3